



[Billing Code 4140-01-P]

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

Draft Report on Carcinogens Monographs on Five Viruses; Availability of Documents;  
Request for Comments; Notice of Peer-Review Meeting

**SUMMARY:** The notice announces a meeting to peer review Draft Report on Carcinogens (RoC) Monographs on Five Viruses: Epstein-Barr virus [EBV], human immunodeficiency virus type 1 [HIV-1], human T-cell lymphotropic virus type 1 [HTLV-1], Kaposi sarcoma-associated herpesvirus [KSHV], and Merkel cell polyomavirus [MCV]. The monographs were prepared by the Office of the Report on Carcinogens (ORoC), Division of the National Toxicology Program (DNTP), National Institute of Environmental Health Sciences (NIEHS). The peer-review meeting is open to the public. Registration is requested for both public attendance and oral comment and required to access the webcast. Information about the meeting and registration is available at <http://ntp.niehs.nih.gov/go/38853>.

### DATES:

Meeting: December 17, 2015, 8:30 AM Eastern Standard Time (EST) to adjournment.

Document Availability: Draft monographs should be available by the week of November 2, 2015, at <http://ntp.niehs.nih.gov/go/38853>.

Written Public Comments Submissions: Deadline is December 3, 2015.

Registration for Attendance and/or Oral Comments: Deadline is December 10, 2015. Registration to view the meeting via the webcast is required.

#### ADDRESSES:

Meeting Location: Rodbell Auditorium, Rall Building, NIEHS, 111 T.W. Alexander Drive, Research Triangle Park, NC 27709.

Agency Meeting Website: The draft monographs, draft agenda, registration, and other meeting materials will be posted at <http://ntp.niehs.nih.gov/go/38853>.

Webcast: The URL for viewing the webcast will be provided to those who register.

FOR FURTHER INFORMATION CONTACT: Dr. Lori White, NTP Designated Federal Official, Office of Liaison, Policy, and Review, DNTP, NIEHS, P.O. Box 12233, MD K2-03, Research Triangle Park, NC 27709. Phone: (919) 541-9834, Email: [whiteld@niehs.nih.gov](mailto:whiteld@niehs.nih.gov). Hand Delivery/Courier: 530 Davis Drive, Room 2124, Morrisville, NC 27560.

#### SUPPLEMENTARY INFORMATION:

**Background:** The RoC is a congressionally mandated, science-based, public health report that identifies agents, substances, mixtures, or exposures (collectively called

"substances") in our environment that pose a cancer hazard for people in the United States. The NTP prepares the RoC on behalf of the Secretary of Health and Human Services.

The NTP follows an established, four-part process for preparation of the RoC (<http://ntp.niehs.nih.gov/go/rocprocess>). A RoC monograph is prepared for each candidate substance selected for review for the RoC. A draft RoC monograph consists of (1) a cancer hazard evaluation component that reviews all information that may bear on a listing decision, assesses its quality and sufficiency for reaching a listing decision, applies the RoC listing criteria to the relevant scientific information, and recommends a listing status for the candidate substance in the RoC and (2) a substance profile that contains the NTP's preliminary listing recommendation and a summary of the scientific evidence considered key to reaching that recommendation.

Five viruses, EBV, HIV-1, HTLV-1, KSHV, and MCV, were selected as candidate substances following solicitation of public comment, review by the NTP Board of Scientific Counselors on April 16 - 18, 2014, and approval by the NTP Director (<http://ntp.niehs.nih.gov/go/9741>). A RoC monograph was prepared for each virus and this meeting is planned for peer review of the five draft RoC monographs.

Approximately 10% of cancers in the United States and 17.8% worldwide are linked to infectious disease. Several viruses, including hepatitis B virus, hepatitis C virus, and some human papilloma viruses of the genital-mucosal type, are currently listed in the RoC as known to be human carcinogens. NTP is conducting an evaluation of the following five viruses for possible listing in the RoC: EBV and KSHV, which are herpesviruses; MCV, which is a recently discovered polyomavirus; and HIV-1 and

HTLV-1, which are retroviruses. HIV and HTLV-1 infection occurs from sexual, parenteral, and perinatal transmission, whereas transmission via saliva is a common route of exposure for KSHV and EBV. Although MCV is found in the skin and saliva, it is not clear how people are infected. Additional information about the evaluation of these viruses for the RoC is available at <http://ntp.niehs.nih.gov/go/733995>.

**Meeting and Registration:** This meeting is open to the public with time set aside for oral public comment. The public may attend the meeting at NIEHS, where attendance is limited only by the space available, or view the webcast. Registration is required to view the webcast; the URL for the webcast will be provided in the email confirming registration. Individuals who plan to provide oral comments (see below) are encouraged to register online at the meeting website (<http://ntp.niehs.nih.gov/go/38853>) by December 10, 2015, to facilitate planning for the meeting.

The preliminary agenda and draft monographs should be posted on the NTP website (<http://ntp.niehs.nih.gov/go/38853>) by the week of November 2, 2015. Additional information will be posted when available or may be requested in hardcopy, see FOR FURTHER INFORMATION CONTACT. Following the meeting, a report of the peer review will be prepared and made available on the NTP website. Interested individuals are encouraged to access the meeting website to stay abreast of the most current information regarding the meeting.

Visitor and security information is available at <http://www.niehs.nih.gov/about/visiting/index.cfm>. Individuals with disabilities who need accommodation to participate in this event should contact Ms. Robbin Guy at

phone: (919) 541-4363 or email: [guyr2@niehs.nih.gov](mailto:guyr2@niehs.nih.gov). TTY users should contact the Federal TTY Relay Service at (800) 877-8339. Requests should be made at least five business days in advance of the event.

**Request for Comments:** The NTP invites written and oral public comments on the draft monographs. The deadline for submission of written comments is December 3, 2015, to enable review by the peer-review panel and NTP staff prior to the meeting. Registration to provide oral comments is by December 10, 2015, at <http://ntp.niehs.nih.gov/go/38853>. Public comments and any other correspondence on the draft monographs should be sent to the FOR FURTHER INFORMATION CONTACT. Persons submitting written comments should include their name, affiliation (if applicable), phone, email, and sponsoring organization (if any) with the document. Written comments received in response to this notice will be posted on the meeting website, and the submitter identified by name, affiliation, and/or sponsoring organization.

Public comment at this meeting is welcome, with time set aside for the presentation of oral comments on the draft monographs. In addition to in-person oral comments at the meeting at the NIEHS, public comments can be presented by teleconference line. There will be 50 lines for this call; availability will be on a first-come, first-served basis. The lines will be open from 8:30 AM until adjournment on December 17, 2015; oral comments will be received only during the formal public comment period indicated on the preliminary agenda. Each organization (sponsoring organization or affiliation) is allowed one time slot. At least 7 minutes will be allotted to

each speaker, and if time permits, may be extended to 10 minutes at the discretion of the chair.

Persons wishing to make an oral presentation are asked to register online at <http://ntp.niehs.nih.gov/go/38853> by December 10, 2015, and if possible, to send a copy of their slides and/or statement or talking points at that time. Written statements can supplement and may expand the oral presentation. Registration for in-person oral comments will also be available at the meeting, although time allowed for presentation by on-site registrants may be less than that for registered speakers and will be determined by the number of speakers who register on-site.

**Background Information on the RoC:** Published biennially, each edition of the RoC is cumulative and consists of substances newly reviewed in addition to those listed in previous editions. For each listed substance, the RoC contains a substance profile, which provides information on cancer studies that support the listing—including those in humans, animals, and studies on possible mechanisms of action—information about potential sources of exposure to humans, and current federal regulations to limit exposures. The 13<sup>th</sup> RoC, the latest edition, was published on October 2, 2014 (available at <http://ntp.niehs.nih.gov/go/roc13>), and the 14<sup>th</sup> RoC is under development.

**Background Information on NTP Peer-Review Panels:** NTP panels are technical, scientific advisory bodies established on an "as needed" basis to provide independent scientific peer review and advise the NTP on agents of public health concern, new/revised toxicological test methods, or other issues. These panels help ensure

transparent, unbiased, and scientifically rigorous input to the program for its use in making credible decisions about human hazard, setting research and testing priorities, and providing information to regulatory agencies about alternative methods for toxicity screening. The NTP welcomes nominations of scientific experts for upcoming panels. Scientists interested in serving on an NTP panel should provide a current curriculum vitae to the FOR FURTHER INFORMATION CONTACT. The authority for NTP panels is provided by 42 U.S.C. 217a; section 222 of the Public Health Service (PHS) Act, as amended. The panel is governed by the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), which sets forth standards for the formation and use of advisory committees.

Dated: October 7, 2015

John R. Bucher, Ph.D.

Associate Director, NTP

[FR Doc. 2015-26050 Filed: 10/13/2015 08:45 am; Publication Date: 10/14/2015]